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EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/234,606	Applicant(s) Wolff
	Examiner Dave Nguyen	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 18, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1 and 3-20* is/are pending in the application.

4a) Of the above, claim(s) *18-20* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 3-17* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Applicant's election of Group I claims, claims 1, and 3-17, in the response filed October 18, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed error in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claimed invention.

Claims 1, and 3-17, to which the following grounds are applicable, are pending.

The drawings are objected because of the PTO-948 attached to the office action dated 2/15/000. **A complete response to this office action must include a response to the objection or a filing of corrected drawings so as to obviate the objection.**

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-17 readable on a genus of chelators, which not only must exhibit the ability to electrostatically complexed with a nucleic acid but also to able to carry the nucleic acid across the cell membrane of a target cell; and/or readable on any polymer other than nucleic acid which must exhibit the property of being transcribed and/or translated into a desire product, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

With respect to the issue of a generic chelator as claimed, it is acknowledged that the as-filed specification defined the term "chelator" as being any polydentate ligand, *e.g.,* a chemical compound or molecule that exhibits the ability to occupy more than one site in the coordination sphere of an ion.

However, the as-filed specification only provides sufficient description of chelator-polycationic polymer, which must exhibit the ability to electrostatically bind to an expressible nucleic acid polymer. The as-filed specification does not provide sufficient written description of a representative number of species of polydentate ligands having a specifically named structure so as to exhibit any of the biological property as intended by applicants. Present claims relate to an extremely large number of possible compounds which not only acts as polydentate ligand but also to be able to complex electrostatically with a nucleic acid and subsequently enhance the delivery of a nucleic acid across the cell membrane of a target cell. The as-filed description coupled with the state of the prior art only provide sufficient description of a chelator-polycationic polymer, *e.g.,* a crown ether based chelators or polychelator complexed with polylysine, s for use within the context of the claimed invention, *e.g.,* enhance the delivery and expression of a desired nucleic acid.

With respect to the issue of claiming generically an expressible polymer, the as-filed specification only provides a description of one species of an expressible polymer as generically claimed, *e.g.,* an expressible nucleic acid. It is apparent that on the basis of applicant's disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or assays and/or any other unspecified structure containing unspecified compounds that are yet to be discovered but embraced the claimed invention, wherein the detailed and a substantially and specifically common structure of the genera of the claimed compounds were not described; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structure(s) of component(s) that are linked structurally to the extent that the described structures with essential elements must be able to reflect any of the disclosed biological functions as contemplated by the as-filed specification. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. It appears that only nucleoside is and its making are conventional in the state of the prior art and are disclosed in the as-filed disclosure. Claiming unspecified molecular structures of material(s) or claiming compounds without an adequate written description of essential

elements of the compounds in order to exhibit applicant's intended claimed property, *e.g.*, nucleic acid enhanced delivery and expression, and/or an expressible polymer, without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

With respect to dependent claim 8, which further defines the claimed chelator as being only a "polyamine", a close and careful review of the as-filed specification only provides a sufficient written support for a crown ether based chelator or polychelator containing polyamine, a polyamine which has been modified to incorporate a chelator a plurality of chelators. A claim of the "a chelator consists of a polyamine", which is interpreted as an naturally occurring polyamine, *polylysine,* which is not necessarily modified to have a crown ether based chelator incorporated within the polyamine, does not appear to have any written support from the as-filed specification. Thus, this is new matter and applicant is required to amend the claims to overcome the new matter issue.

Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Claims 1, 3-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to:

1) A process for delivering a nucleic acid polymer to a cell, *in vivo,* comprising:
    a) Assisting delivery to the cell by electrostatically associating a polycation comprising a chelator with the nucleic acid polymer;

b) Delivering the chelator polycation/nucleic acid polymer complex to the inside of the cell; whereby the nucleic acid is expressed in the cell.

2) A process for delivering a nucleic acid polymer to a cell, *in vivo,* comprising:

a) Forming a polychelator by covalently polymerizing chelator containing cationic monomers;

b) Electrostatically associating the polychelator with the nucleic acid polymer to form a complex;

c) Delivering the complex to the cell, whereby the nucleic acid polymer is expressed in the cell.

3) A process for delivering a polymer to a cell, comprising:

a) electrostatically associating a polychelator containing polycation to the polymer;

b) recharging the associated polychelator to change the net charge; and,

c) delivering the associated polymer/polychelator to the cell.

The specification does not reasonably provide enablement for the presently pending claims encompassing any and/or all structure other than those as indicated in the enabling embodiments. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in In re Wands, 858 F.2d 731, 8USPQ2d 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Specifically, since the claimed invention is not supported by a sufficient written description (for possessing of the genus of chelator, polychelator, and/or expressible polymers as intended by the as-filed specification), particularly in view of the reasons set forth above, one skilled in the art would not known how

to use and make the claimed invention so that it would operate as intended within the context of applicant's claimed invention.

Furthermore, the presently pending claims embrace an embodiment wherein the delivery step encompasses not only the delivery of a chelator containing polycation/nucleic acid polymer complex but also a nucleic acid by itself even when the step of associating the chelator to the nucleic acid polymer already has been carried out. The as-filed specification only provides sufficient guidance for the delivery step directed essentially to delivering the chelator/nucleic acid polymer complex to a cell. As such, the claims should be amended to reflect the step in order to obviate the rejection. With respect to the issue of "expressing the polymer" containing step, the as-filed specification only provides sufficient guidance to the making and use of an expressible nucleic acid polymer, wherein the active step of delivering the nucleic acid/chelator or nucleic acid/polychelator is carried out, whereby the nucleic acid as a result of being carried across into a target cell is expressed intracellularly. The claims as pending contemplate any active step of expressing any polymer including those of nucleic acid polymers. However, other than an intracellular expression of a nucleic acid as a result of the presence of regulatory elements and coding sequences of a nucleic acid in an expression cassette present in the nucleic acid polymer, the as-filed specification does not teach any active step of "expressing the polymer" as embraced by the claims. As such, other than the enabling embodiments with respect to a natural expression of an expression cassette present in an expressible nucleic acid, it is not apparent how a skilled artisan, without any undue experimentation, practices the claimed active step of expressing any polymer in any way as broadly claimed, particularly on the basis of applicant's disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 3, 6-14, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative, under 35 USC 103(a) as being unpatentable over Kayyem *et al.,* (WO 96/11712, IDS).

Kayyem teaches a process for delivery an anionic polymer (DNA)-cationic polymer complex conjugated to a plurality of chelators bound to a contrast agent (page 8, first and second paragraphs; page 9, second paragraph, page 10, third paragraph, page 11, second paragraph, pages 12 and 13, and pages 26-32. Kayyem teaches that a plurality of chelators can be added to the -NH2 groups of the lysine side chains as linkers for binding to a plurality of contrast agents (page 10, third paragraph), and that a chelator can be conjugated to any of the disclosed polymeric molecule (page 12). Cell targeting moieties and physiological agents, including contrast agents and therapeutic agents, are attached to one or both of the polymeric molecules (abstract). Furthermore, the abstract clearly states:

> The delivery vehicles can be used in clinical protocols in which nucleic acids for gene therapy [expressible nucleic acids] and agents for MRI contrast are co-transported to specific cells allowing medical imaging monitoring of nucleic acid delivery.

(Also see page 4, lines 16-22).

On page 5, Kayyem states that "In another embodiment, one of the polymeric molecules comprises a nucleic acid which is complexed [electrostatically] with one or more polymeric molecules comprising a polyamine.

With respect to the limitation of recharging the polychelator to change the net charge and the limitation of an expressible nucleic acid being a first polyanionic polymer or molecule, Kayyem teaches the same on pages 7 and 8. More specifically, Kayyem states:

> The delivery of the present invention comprise a fist polymeric molecule [expressible nucleic acid] and a second polymeric molecule [polycationic molecule, a complex composed of polylysine and a chelator, see page 10]. As indicated in Figure 1A, the delivery vehicle (1) comprises a first polymeric molecule (2) having an overall net positive or negative charge which is employed as a scaffold to which an oppositely charged second polymeric molecule (3) is complexed. As shown in Figure 1B, some delivery vehicles include a third polymeric molecule (6) having a net charge opposite that of the first polymeric molecule and complexed with the first polymeric molecule. Preferably the first and second polymeric molecules are held together by electrostatic interactions and thus do not need to be covalently linked to each other. In certain embodiments, both the first and second polymeric molecules contain a mixture of charged groups and thus are zwitterionic. The depiction of linear polymeric molecules in Figure 1 is for illustrative purposes and is not necessarily preferred, as circular polymers such as plasmids [expressible nucleic acids] may also be used. The delivery vehicle will be in any configuration that is suitable for cellular uptake. (page 7);
>
> In a preferred embodiment, the nucleic acid is double stranded, most preferably a double stranded plasmid (page 8).

Thus, Kayyem does teach that the second polymeric molecule can be recharged by preparing the molecule so as to contain a mixture of charged groups and/or by complexing a third polymeric molecule to the nucleic acid polymer.

More specifically as to the expressible plasmid, Kayyem states on page 8:

In one embodiment, the nucleic acid encodes a reporter gene, such that the uptake of the delivery vehicle can be additionally monitored by the presence or absence of the reporter gene and/or the protein encoded by the gene [protein expressed by the nucleic acid].

More specifically as to the use of the delivery vehicle to deliver and express a therapeutic protein encoded nucleic acids for gene delivery and/or gene therapy, Kayyem teaches the same on page 8 through page 9.

More specifically as to the second polymeric molecule being a modified polysine composed of lysine/chelator based monomers linked by a covalent bond, Kayyem teaches on page 10:

When polylysine is used as the second polymeric molecule, the –NH2 group of the lysine side chains at high pH serve as strong nucleophiles for multiple attachment of activated chelating agents. The invention takes advantage of both the polycationic and polynucleophilic nature of polyamines such as polysine. At high pH the lysine monomers are coupled to the physiological agents under conditions that yield on average 5-20% monomer substitutions. At physiological pH to low pH, the remaining unlabeled positively charged lysines facilitate nucleic acid bindings.

As to the linkage of cell targeting agents and/or physiological agents, Kayyem states on page 11:

The cell targeting moieties and physiological agents described below are attracted to either polymeric molecule, although in a preferred embodiment they are both attached to the polycation.

In addition and to particularly point out that the invention is not directed *per se* to just the delivery of contrast agents such as paramagnetic or superparamagnetic metals, Kayyem states clearly on the first paragraph of page 12:

By the term "physiological agent" herein is meant compounds which are desirable to deliver in a cell-specific manner. Included in this definition of physiological agents are both contrast agents and therapeutic agents.

Kayyem also recognizes the toxicity of the use of some paramagnetic or superparamagnetic metals as contrast agents, and further provide a solution to the problem by teaching on page 12:

Gd(III) ions are extremely toxic to cells and therefore must be bound to a chelating agent which is then conjugated to the polymeric molecule [second polymeric molecule, for example].

A number of chelating agents is further taught by Kayyem as being disclosed in a number of US patents as cited on page 12 of Kayyem.

In addition, Kayyem discloses on page 26 that pharmaceutically acceptable carriers including a salt are employed in the preparation of a conjugate of chelators and a cationic polymer.

Absent evidence to the contrary, the delivery process and the compositions or conjugates disclosed in Kayyem have all of the properties cited in the claims, and to the extent that any minor modification such that types of bonding and/or an incorporation of more charges so as positive charges are abundant to enhance the delivery of nucleic acid into target cells, it would have been obvious for one of ordinary skill in the art have modified such changes so long as such modifications are within the teaching of the Kayyem reference so as provide addictive effects in enhancing the delivery of the nucleic acid into a target cell for expression.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be

> patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kayyem *et al.* taken with Hnatowich *et al.* (US Pat No. 5,980,861).

To the extent that Kayyem does not teach explicitly crown ether or polymers associated with a plurality of crown ether chelators, Hnatowich teaches that it is routine in the art at the time the invention was made for one of ordinary skill in the art to employ known chelators including crown ether for conjugation to a polymer either by covalent bonding or ionic bonding for purpose of real time monitoring of the delivery of polymers including DNA (entire document, especially columns 11 and 12). In addition, Hnatowich teaches that crown ether chelators can be covalently bound to the anionic polymer (DNA) through the nitrogen atom that is provided on the nucleic acid, or through other functional moieties bound to the anionic polymer (column 12). More specifically, Hnatowich *et al.* teach on column 2 bridging column 3; column 3 bridging column 4; column 6, last paragraph; column 9, first paragraph; column 11, lines 1 to lines 54; column 12 bridging column 13; column 19, first paragraph; and columns 43 and 44:

A process for delivery of radiolabeled nucleic acid molecules or radiolabeled peptide nucleic acid to a cell, which process comprises associating a crown ether to either a nucleic acid polymer or a peptide nucleic acid polymer through a polyamine linker (which is positive charged within its own biochemical structure), mixing the crown ether containing nucleic acid polymer with a polymer carrier, and delivering the crown ether containing nucleic acid polymer complexed with the polymeric polymer to a cell. As a result of

the teaching provided by the Hnatowich *et al.* reference, the crown ether based chelator is electrostatically linked to a cDNA by a positive charged linker, *e.g.,* polyamine. Not only that '861 patent teach complexes of nucleic acid molecules associated with a chelator, the patent on column 19 further teaches that polymeric carriers including polyglycolic acid can be associated or linked to the DNA-chelator complex as controlled release formulation to enhance the delivery of DNA polymer to a target cell.

It would have been obvious for one of ordinary skill in the art to employ any chelator including crown ether bound to polylysine in the conjugate or composition of Kayyem. One of ordinary skill in the art would have been motivated to have employed crown ether as a chelator or polychelator for the purpose of either conjugating covalently to the -NH2 moiety of the cationic polymer such as polylysine because Hnatowich teaches that chelator moieties of crown ether are known in the prior art as effective chelators for use in real time monitoring of the delivery of polymers to cells *in vivo,* and because Kayyem *et al.* teaches that any of the known paramagnetic metal ion chelators attached covalently to the -NH2 moiety of the cationic polymer such as polylysine can be used for the purpose of real time monitoring of the delivery of polymers including expressible to target cells *in vivo* for the purpose of gene delivery and/or gene therapy set forth in any prior art.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicant in the response (page 5 in the response filed May 22, 2001) mainly asserts that the limitation of *in vivo* expression is not taught in Kayyem, that the utilization of a chelator taught in Kayyem is not the same as that of applicant which is to function is a process step for *in vivo* delivery. Applicant's assertion is not found persuasive because of the reasons set forth in the above stated rejection. The limitation of *in vivo* expression is taught in Kayyem as evidenced by the cited paragraphs. Note that Kayyem clearly teaches that chelators or a polychelator bound electrostatically to a polylysine together with a contrast agent, which is then complexed to a nucleic acid delivery and expressible nucleic acid vector, *e.g.,* plasmid, and that the entire delivery complex is subsequently employed for gene delivery to any target cell

include those cells suitable for gene therapy. In view of the teaching as summarized in the stated rejection and in the preceding sentence, the examiner maintains that Kayyem does teach that the chelator/contrast agent/polylysine/nucleic acid vector is employed for gene delivery and expression in any context including gene therapy (*in vivo*) and thereby would function in a process step for *in vivo* delivery.

The following prior art is further cited to indicate that modified polylysine comprising a polyether and an active substance is known to enhance the concentration of the substance at a desired target site:

US Pat No. 6,395,254 B1.

No claim is allowed.

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Tiffiany Tabb, whose telephone number is **(703) 605-1238.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Trong Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER